REMARKS

Reconsideration and withdrawal of the rejections of this application, and, if necessary, an early interview with the Examiner, are respectfully requested in view of the remarks herein. The Examiner is thanked for reconsidering the required election of species and broadening the searched species.

I. STATUS OF THE CLAIMS AND FORMAL MATTERS

Claims 1-19 are pending. Claim 19 has been added, without prejudice, without admission, without surrender of subject matter, and without any intention of creating any estoppel as to equivalents.

No new matter is added.

It is submitted that these claims are in full compliance with the requirements of 35 U.S.C. §112. The additions to the claim and the remarks herein are not made for the purpose of patentability within the meaning of 35 U.S.C. §§ 101, 102, 103 or 112; but rather the amendments and remarks are made simply for clarification and to round out the scope of protection to which Applicants are entitled.

It is also respectfully submitted that the amendments to the specification herein constitute no new matter. The specification has been amended to include the recitation that the naked DNA can include a promoter, origin of replication, and transcription termination sequence. Support for the amended paragraph is found on page 1, line 10, wherein International Patent WO 95/11307 is referenced as a source of information relating to polynucleotide vaccines. The preliminary amendment filed with the application on October 2, 2000 added a paragraph to the specification incorporating by reference all patents, applications and documents cited in the present application, including WO 95/11307 (see page 2 of the preliminary amendment, paragraph entitled "Cross-Reference to Related Applications/Incorporation by Reference").

International Application WO 95/11307 includes, at page 4, lines 27 to 30, reference to the inclusion of an origin of replication. Further, at page 6, lines 24 to 26, the inclusion of a transcription termination sequence is discussed. As the inclusion of a promoter is noted in the present application (see for example, page 10, lines 26-29), proper support for the amended paragraph is found either in the present specification, or in WO 95/11307, incorporated therein

by reference through the preliminary amendment filed with the present application on October 2, 2000. The inclusion of the amended recitation serves only to more accurately describe naked DNA as known to one of skill in the art, and as known at the time of filing the present application.

On July 29, 2003, Applicants resubmitted a verified English translation of the French priority application. Accordingly, it is respectfully believed that Applicants' claim of foreign priority is substantiated, and that Applicants are accordingly entitled to a priority date of April 3, 1998. If any impediment to the priority claim remains, Applicants request that the Examiner inform Applicants of the same, so that deficiency may be promptly corrected.

II. THE ART REJECTIONS ARE OVERCOME

Claims 1, 2, 4, 10, 11, and 12 were rejected under 35 U.S.C. §102(e) as allegedly anticipated by Ross (U.S. Patent No. 6,444,799). The rejection is respectfully traversed.

As described above, the previously submitted verified English translation of the French priority application is believed to have perfected Applicants claim of priority, entitling Applicants to a filing date of April 3, 1998, which is prior to the filing of Ross. Accordingly, Ross is not a proper 102 reference, and the rejection is therefore improper. Consequently, reconsideration and withdrawal of the rejection under 35 U.S.C. §102(e) is respectfully requested.

Claims 1-14, to the extent they embrace FIV DNA vaccines, were rejected under 35 U.S.C. §102(e) as allegedly anticipated by Chavez (U.S. Patent No. 6,300,118). The rejection is respectfully traversed.

Initially, it is respectfully pointed out that for a Section 102 rejection to stand, the single prior art reference must contain all of the elements of the claimed invention, *see Lewmar Marine Inc. v. Barient Inc.,* 3 U.S.P.Q.2d 1766 (Fed. Cir. 1987), and, the single prior art reference must contain an enabling disclosure, *see Chester v. Miller,* 15 U.S.P.Q.2d 1333, 1336 (Fed. Cir. 1990).

The present invention is directed towards a DNA vaccine comprising a naked DNA containing and expressing *in vivo* a polynucleotide encoding an antigenic polypeptide and at least one adjuvant that is a polymer of acrylic or methacrylic acid or a copolymer of maleic anhydride and alkenyl.

In contrast, Chavez relates to a vaccine comprising recombinant FIV empty capsids encoding a deleted FIV RNA genome in combination with EMA or Carbopol®. It is respectfully submitted that the rejection is improper because Chavez does not teach or suggest use of naked DNA in a vaccine.

Accordingly, reconsideration and withdrawal of the rejection under 35 U.S.C. §102 is respectfully requested.

Claims 1-18were rejected under 35 U.S.C. 103(a) as allegedly unpatentable over Davis (U.S. 2002/0164341), Olsen (US 2001/0007860) or Crabb (U.S. 5,922,237) taken with any of Miles, Inc. (EP 0 532 833 A1), Lowell (WO 95/11700), Chavez, Gicquel (US 2001/0024653) or Wasmoen (US 5,989,562). The rejection is respectfully traversed.

It is well-settled that there must be some prior art teaching which would have provided the necessary incentive or motivation for modifying the reference teachings. *In re Laskowski*, 12 U.S.P.Q. 2d 1397, 1399 (Fed. Cir. 1989); *In re Obukowitz*, 27 U.S.P.Q. 2d 1063 (BOPAI 1993). Further, "obvious to try" is not the standard under 35 U.S.C. §103. *In re Fine,* 5 U.S.P.Q. 2d 1596, 1599 (Fed. Cir. 1988). And, as stated by the Court in *In re Fritch*, 23 U.S.P.Q. 2d 1780, 1783-1784 (Fed. Cir. 1992): "The mere fact that the prior art may be modified in the manner suggested by the Examiner does not make the modification obvious unless the prior art suggests the desirability of the modification." Also, the Examiner is respectfully reminded that for the Section 103 rejection to be proper, **both the suggestion of the claimed invention and the expectation of success must be founded in the prior art, and not Applicants' disclosure**. *In re Dow*, 5 U.S.P.Q.2d 1529, 1531 (Fed. Cir. 1988).

The Office Action admits that Davis, Olsen and Crabb do not teach "an incorporation of EMA or Carbopol® as adjuvants in the DNA vaccine composition so as to enhance its vaccinated effect."

Miles relates to an inactivated EHV vaccine.

Lowell relates to antigen (protein) vaccines.

Chavez relates to plasmids encoding an RNA FIV genome as a vaccine.

Gicquel relates to genetically attenuated mycobacaterium strains as vaccines.

Wasmoen relates to recombinant raccoon poxvirus as a vaccine.

All of the secondary documents cited (Miles, Lowell, Chavez, Gicquel, and Wasmoen) relate to classical vaccines—vaccines that upon administration present an epitope or antigen to the immune system—or RNA vaccines, in which an entire or deleted genome is administered. In contrast, the present invention is a naked DNA vaccine that expresses an epitope or antigen *in vivo*. That the adjuvants of the instant claims so function to enhance immunogenicity of that which is expressed by the DNA vaccine is surprising and unexpected; and, there is no motivation from the cited documents to employ the adjuvants of the instant claims to DNA plasmid vaccines. Simply, while the secondary documents describe the use of adjuvants, they do not provide any suggestion or motivation that would cause one of skill in the art to apply their teachings to DNA plasmid vaccines. Similarly, Davis, Olsen and Crabb do not provide any suggestion or motivation that would cause one of skill in the art to apply methods associated with classical or RNA vaccines to DNA plasmid vaccines and expect to have any chance of success. The motivation to combine with any expectation of success is missing from all of the cited documents.

Applicants respectfully direct the Examiner's attention to the enclosed graphs which demonstrate results obtained after vaccinating horses and pigs with naked DNA containing and expressing *in vivo* a polynucleotide encoding an antigenic polypeptide of EHV-1 and PRV, respectively, both with and without the addition of Carbopol®. Although the neutralizing antibodies after vaccination with PRV were lower when Carbopol® was present in the vaccine, pigs vaccinated with naked DNA and Carbopol® had less weight loss than those vaccinated with only naked DNA.

Further, the graphs depicting the results from EHV-1 indicate that the general trend was that animals vaccinated with naked DNA and Carbopol® had higher levels of neutralizing antibodies and lower virus excretion than those vaccinated with naked DNA only. And, animals vaccinated with naked DNA and Carbopol® had a lower percentage of positive viral isolation by the end of the 21 day period.

As shown in the accompanying charts, the addition of Carbopol® to the naked DNA vaccine provides enhanced results that are not evident, and would not be inferred, from any of the documents cited in the Office Action. If it is preferred by the Office, Applicants can submit a declaration attesting to these results.

As the documents cited in the Office Action do not teach or suggest that an incorporation of EMA or Carbopol® as adjuvants in a naked DNA vaccine composition will enhance its vaccinated effect, the Section 103 rejections cannot stand.

Accordingly, reconsideration and withdrawal of the rejections under 35 U.S.C. §103 are respectfully requested.

REQUEST FOR INTERVIEW

If any issue remains as an impediment to allowance, prior to issuance of any paper other than a Notice of Allowance, an interview is respectfully requested; and, the Examiner is respectfully requested to contact the undersigned to arrange a mutually convenient time and manner for such an interview.

CONCLUSION

In view of the amendments, remarks and documents herewith, Applicants have addressed and overcome all rejections of the application set forth in the Office Action, and the present application is in condition for allowance.

Thus, early and favorable reconsideration and withdrawal of the rejections of the application as set forth in the Office Action, and, prompt issuance of a Notice of Allowance of claims 1-18, or an interview with supervisory review, at an early date, with a view towards reaching agreement on allowable subject matter, are earnestly solicited.

Respectfully submitted,

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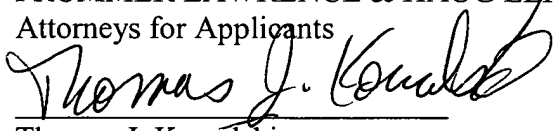
By: 

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